K072899

## C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(in Accordance with SMDA of 1990)

**Aesculap Orthopilot 2 THA V 3.0**
8 October 2007

FEB - 6 2008

**COMPANY:** Aesculap®Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

**CONTACT:** Matthew M. Hull
800-258-1946 x 5072 (phone)
610-791-6882 (fax)

**TRADE NAME:** Aesculap Orthopilot 2 THA V 3.0

**COMMON NAME:** Surgical Navigation Platform

**DEVICE CLASS:** Class II

**PRODUCT CODE:** 84 HAW

**CLASSIFICATION:** 882.4560 – Stereotaxic Instrument

**REVIEW PANEL:** Neurology

### INDICATIONS FOR USE

The Orthopilot® 2 Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to optimally position endoprosthesis in arthroplasty such as the Search Evolution Knee system and the Gem Knee system in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for total endoprosthesis replacement surgery and provides intraoperative measurements of bone alignment. It indicates optimized angles and positions for implant placement.

### DEVICE DESCRIPTION

The Total Hip Arthroplasty (THA) software module version 3.0 is an upgrade to the THA version 2.0 that was cleared for the Aesculap Orthopilot 2. It is designed to provide computer aided navigation for total hip arthroplasty using Aesculap's Orthopilot 2 platform. The Orthopilot 2 uses transmitters that are mounted to the patients bones, or are mobile to palpate anatomical landmarks in conjunction with a camera to monitor the spatial location of the transmitters in relation to each other and/or instruments. THA version 3.0 also allows for the use of ultrasound to provide data for anatomical landmarks.

### PERFORMANCE DATA

No applicable performance standards have been promulgated under FDCA Section 514 for this system. This software module was developed in accordance with Aesculap's internal SOP's as well as CDRH's "General Principles of Software Validation; Final Guidance for Industry and FDA Staff. Aesculap's Orthopilot 2 Navigation platform does comply with the following FDA recognized standards:

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|---|---|
| IEC 60601-1 | International Electrotechnical Commission; Medical Electrical Equipment, Part 1: General Requirements for Safety. |
| IEC 60601-1-2 | International Electrotechnical Commission; Medical Electrical Equipment, General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests. |

## SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the Orthopilot 2 THA Software Module 3.0 is substantially equivalent to our currently marketed THA Module 2.0 that was cleared in Aesculap's 510(k) submission #K050752 and THA Module 1.0 in the original submission #K013569 for Orthopilot 2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Aesculap Implant Systems, Inc.
% Mr. Matthew M. Hull
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K072899
Trade/Device Name: Aesculap Orthopilot 2 THA Module V 3.0
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: January 8, 2008
Received: January 9, 2008

Dear Mr Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## B. INDICATIONS FOR USE STATEMENT

**510(k) Number:** K072899

**Device Name: Aesculap Orthopilot 2 THA Module V 3.0**

**Indication for Use:**

The Orthopilot® 2 Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to optimally position endoprosthesis in arthroplasty such as the Search Evolution Knee system and the Gem Knee system in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for total endoprosthesis replacement surgery and provides intraoperative measurements of bone alignment. It indicates optimized angles and positions for implant placement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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